IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
ANDERSON DIVISION

Dolores Viserta,	)	
	)	
Plaintiff,	)	C.A. No. 8:11-cv-00505-JMC
	)	
v.	)	**ORDER AND OPINION**
	)	
St. Jude Medical, Inc.,	)	
	)	
Defendant.	)	
_____	)	

This matter is before the court on Defendant St. Jude Medical, Inc.'s ("St. Jude") Motion to Dismiss [Doc. 14] Plaintiff's Amended Complaint. Based upon the record before the court and after having considered the arguments of counsel, Defendant's Motion to Dismiss is granted.

FACTUAL BACKGROUND

Plaintiff Delores Viserta ("Viserta") brings this action alleging that St. Jude manufactured, distributed, and sold a medical device which did not conform to the specifications approved by the Federal Drug Administration (FDA), and that the product nonconformities and/or defects caused her injury.

St. Jude manufactures cardiac defibrillators and defibrillator leads which are implanted into the chest of cardiac patients. Leads are insulated, wire-like devices that connect the implantable defibrillators directly to a patient's heart. St. Jude manufactured a lead known as the Riata Model 1560 lead ("Riata Lead"). The Riata Lead is a Class III medical device that the FDA approved through the pre-market approval ("PMA") process under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq*., to the Food, Drug & Cosmetic Act ("FDCA").

Viserta was implanted with a Riata Lead in September of 2007. In May of 2009, Viserta learned that one of the leads of the defibrillator had perforated her heart. As a result, Viserta

underwent surgery to replace the lead and correct the damage to her heart. The Riata Lead was removed from Viserta and discarded. Viserta alleges that premature abrasion of the silicone insulation shell used on the Riata Lead caused the perforation of her heart. In support of her claims, Viserta alleges that St. Jude used inferior manufacturing materials or inadequate manufacturing procedures, and claims that these materials or procedures did not meet Current Good Manufacturing Practices ("CGMPs") promulgated by the FDA, and/or that they deviated from the FDA's approval for the Riata Lead. Viserta further claims that St. Jude violated a duty to warn of an unreasonable risk of harm created by the allegedly defective silicone insulation shell of the Riata Lead.

St. Jude filed its Motion to Dismiss Plaintiff's Amended Complaint on the grounds that Viserta's claims are preempted by federal law and that, even if not preempted, Viserta has failed to state a claim.

STANDARD OF REVIEW

For a complaint to survive a motion to dismiss, the Federal Rules of Civil Procedure require that it contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Although Rule 8(a) does not require "detailed factual allegations," it requires "more than an unadorned, the-defendant-unlawfully-harmed-me accusation," *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-57 (2007)), in order to "give the defendant fair notice ... of what the claim is and the grounds upon which it rests," *Twombly*, 550 U.S. at 555 (internal citations omitted). Stated otherwise, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 129 S. Ct. at 1949 (quoting *Twombly*, 550 U.S. at 570). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw [a] reasonable inference that the defendant is liable for the misconduct alleged." *Id*. (quoting *Twombly*, 550 U.S. at 556). A

complaint alleging facts which are "merely consistent with a defendant's liability ... stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Id*. (quoting *Twombly*, 550 U.S. at 557, 127 S. Ct. 1955) (internal quotation marks omitted).

In evaluating a motion to dismiss, a plaintiff's well-pleaded allegations are taken as true, and the complaint, including all reasonable inferences therefrom, is liberally construed in the plaintiff's favor. *McNair v. Lend Lease Trucks, Inc.*, 95 F.3d 325, 327 (4th Cir.1996). The court may consider only the facts alleged in the complaint, which may include any documents either attached to or incorporated in the complaint, and matters of which the court may take judicial notice. *Tellabs v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). Although the court must accept the plaintiff's factual allegations as true, any conclusory allegations are not entitled to an assumption of truth, and even those allegations pled with factual support need only be accepted to the extent that "they plausibly give rise to an entitlement to relief." *Iqbal*, 129 S. Ct. at 1950. A court may dismiss a complaint where "after accepting all well-pleaded allegations in the plaintiff's complaint as true and drawing all reasonable factual inferences from those facts in the plaintiff's favor, it appears certain that the plaintiff cannot prove any set of facts in support of his claim entitling him to relief." *Edwards v. City of Goldsboro*, 178 F.3d 231, 244 (4th Cir.1999).

DISCUSSION

St. Jude argues that Viserta's Amended Complaint should be dismissed because her claims are preempted by the MDA and, even if such claims are not preempted, she failed to sufficiently state her claims under the requirements of *Twombly* and *Iqbal*.

Congress enacted the MDA in 1976 in response to the vast amount of litigation which occurred surrounding the Dalkon Shield intrauterine device. *See Walker v. Medtronic, Inc.*, 2012 WL 208036, at 1 (4th Cir. 2012). The purpose of the MDA was to "impose[ ] a regime of detailed federal oversight" governing medical devices. *Id*. (citing *Riegel v. Medtronic, Inc*., 552 U.S. 312, 316 (2008)).

The MDA divides medical devices into separate classes depending on the amount of oversight the government determines is appropriate for the devices. The highest class is Class III, which requires the most oversight. Devices categorized in Class III are generally those devices which are represented to support or sustain human life or are substantially important in preventing impairment of human health. *See* 21 U.S.C. § 360c(a)(1)(C). Class III devices are subject "to premarket approval to provide reasonable assurance of [their] safety and effectiveness." *Id*.

"Premarket approval is a rigorous process," *Riegel*, 552 U.S. at 317 (internal quotation marks omitted), which involves an extensive application, disclosure of all investigations related to the device's safety and effectiveness, disclosure of all ingredients or device components, review of manufacturing processes and facilities, submission of device samples, and submission of device labeling. *See Walker,* 2012 WL 208036, at 2 (citing 21 U.S.C. § 360e(c)(1). After premarket approval is granted, the manufacturer is restricted from making any modifications to the device that may affect safety without further FDA approval. "Manufacturers must report to the FDA when an approved device 'may have caused or contributed to a death or serious injury' or malfunctioned in a way that would make it likely to do so in the future,'" *id*. at 3 (citing 21 U.S.C. § 360i(a)(1)), and "must periodically inform the FDA about data from clinical studies or scientific literature related to the device." *Id*. (citing 21 C.F.R. § 814.84(b)). "The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it

determines that a device is unsafe or ineffective under the conditions in its labeling." *Riegel*, 552 U.S. at 319-20.

The MDA includes an express preemption of certain state law claims against device manufacturers. It provides, in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). In *Reigel*, the Supreme Court held that the FDA's premarket approval scheme for Class III devices represented federal requirements and that any common law tort claim founded on different or additional requirements was preempted by the MDA. 552 U.S. at 324-25. However, the Supreme Court also recognized a narrow exception to this rule of preemption. Common law claims "premised on a violation of FDA regulations" are not preempted because "state duties in such a case 'parallel,' rather than add to, federal requirements." *Id*. at 330.

The parties do not dispute that the Riata Lead is a Class III medical device which was subject to the PMA process under the MDA. Because the FDA has approved the design, manufacturing process, and labeling of the Riata Lead as appropriate and reasonably safe, state common law claims which seek to impose different or additional requirements than those imposed by the FDA on St. Jude would be preempted. However, Viserta primarily alleges that her claims arise out of St. Jude's failure to adhere to the federal standards established by the PMA process and other federal regulations. Because she alleges violations of federal requirements – particularly claims for failure to manufacture the medical device in accordance with the federally approved standards – Viserta's

claims may not be of such character as to impose additional or different standards than those established by the PMA process and may be excepted from preemption as parallel claims.

However, while Viserta has attempted to assert a parallel claim by alleging a manufacturing defect or other noncompliance with federal requirements resulting from the PMA process, the court finds that Viserta has failed to adequately plead any specific facts to support her claims as required by *Twombly* and *Iqbal*. The United States Court of Appeals for the Fourth Circuit has not addressed the sufficiency of a plaintiff's complaint concerning tort claims for medical devices governed by the MDA in the context of the requirements set forth in *Twombly* and *Iqbal*. However, district courts within the Fourth Circuit have found that a plaintiff must allege specific facts as to how a manufacturer violated federal requirements and the causal connection between such violations and the plaintiff's injuries to survive a motion to dismiss. *See Bishoff v. Medtronic Inc*., Civil Action No. 1:09CV171, 2010 WL 4852650, at *2 (N.D. W.Va. Nov. 22, 2010); *Covert v. Stryker Corp.*, No. 1:08CV447, 2009 WL 2424559, at *13 (M.D.N.C. Aug. 5, 2009).

In this case, Viserta makes conclusory allegations concerning defects in St. Jude's manufacturing process, but does not include any factual support as to how St. Jude failed to manufacture the Riata Lead in the manner required by the PMA process. While Viserta does note that the Riata Lead has been the subject of multiple adverse event reports, she does not provide any factual basis to create a plausible causal connection between those reports and her injury. Particularly, Viserta does not even allege that the adverse event reports relate to any specific manufacturing defects that could be plausibly related to her injury. The Amended Complaint is further devoid of any factual allegations concerning the actual condition or observation of the device upon its removal which may possibly provide the required causal connection. Viserta simply concludes that the Riata Lead device used by her physician was defective because she experienced

an injury, because there may have been multiple instances or reports of abrasion in other cases, and because St. Jude developed an alternative device based on different technology. Without specific factual support in her complaint identifying how St. Jude failed to comply with federal requirements in manufacturing her device or identifying any causal connection, Viserta's claims fail to state a plausible claim and must be dismissed. *See id.*

Because the court disposes of St. Jude's motion on the basis of Viserta's failure to state a claim under the standards established by *Twombly* and *Iqbal*, the court declines to address St. Jude's alternative grounds for dismissal.

CONCLUSION

For the foregoing reasons, St. Jude's Motion to Dismiss [Doc. 14] is **GRANTED** without prejudice to Viserta's right to potentially pursue relief for a manufacturing defect or other claim premised on St. Jude's failure, if any, to comply with federal standards; provided that such claim is properly supported by sufficient factual allegations. Dismissal is with prejudice as to any claim premised on standards different from or in addition to the manufacture, design, labeling, warning, and other standards and requirements imposed under the MDA.

IT IS SO ORDERED.

United States District Judge

Greenville, South Carolina
February 29, 2012